# Part VI: Summary of the risk management plan

## Summary of risk management plan for Salmeterol/Fluticasone Genetic

This is a summary of the risk management plan (RMP) for Salmeterol/Fluticasone Genetic. The RMP details important risks of Salmeterol/Fluticasone Genetic, how these risks can be minimised, and how more information will be obtained about Salmeterol/Fluticasone Genetic's risks and uncertainties (missing information).

Salmeterol/Fluticasone Genetic's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Salmeterol/Fluticasone Genetic should be used.

## I. The medicine and what it is used for

Salmeterol/Fluticasone Genetic is authorised for the regular treatment of asthma where use of a combination product (long-acting $\beta_2$ agonist and inhaled corticosteroid) in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short- acting β2 agonist or in patients already adequately controlled on both inhaled corticosteroid and long-acting β2 agonist.

It contains Salmeterol and Fluticasone as the active substances and it is given by pressurized inhalation, suspension.

## II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Salmeterol/Fluticasone Genetic, together with measures to minimise such risks and the proposed studies for learning more about Salmeterol/Fluticasone Genetic's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of Salmeterol/Fluticasone Genetic is not yet available, it is listed under 'missing information' below.

## *II.A List of important risks and missing information*

Important risks of Salmeterol/Fluticasone Genetic are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Salmeterol/Fluticasone Genetic. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | None |
| Important potential risks | None |
| Missing information | None |

## *II.B Summary of important risks*

The safety information in the proposed Product Information is aligned to the reference medicinal product.

## *II.C Post-authorisation development plan*

### II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Salmeterol/Fluticasone Genetic.

### II.C.2 Other studies in post-authorisation development plan

There are no studies required for Salmeterol/Fluticasone Genetic.